UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,061	02/20/2004	Vincent Sullivan	035510/303994(P-5972)	6766

47656 7590 01/25/2007

BECTON, DICKINSON AND COMPANY
ALSTON & BIRD LLP
1 BECTON DRIVE, MC 110
FRANKLIN LAKES, NJ 07417-1880

EXAMINER	
TONGUE, LAKIA J	
ART UNIT	PAPER NUMBER
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/783,061	SULLIVAN ET AL.	
	Examiner	Art Unit	
	Lakia J. Tongue	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *69-75* is/are pending in the application.

4a) Of the above claim(s) *70 and 72-75* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *69 and 71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, Claims 69 and 71, in the reply filed on November 16, 2006 is acknowledged. Claims 70, and 72-75 are withdrawn from further consideration. Claims 1-68 have been canceled. Claims 69 and 71 are under examination.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

3. The use of the trademark Accuspray has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

4. Claim 71 is objected to because of the following informalities: The term 'staphyloccocal' is misspelled. The correct spelling is staphylococcal. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 69 and 71 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 69 is rendered vague and indefinite by the use of the term "therapeutic", as a vaccine, by definition is prophylactic not therapeutic. As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claim 69 is rejected under 35 U.S.C. 102(b) as being anticipated by Ahmed et al. (Microbiol. Immunol., 1994; 38(11): 837-842).

Claim 69 is drawn to a vaccine composition made by a method comprising atomizing a liquid formulation of a therapeutic or prophylactic agent to produce an atomized formulation, freezing said atomized formulation to form solid particles, and drying said solid particles to produce dried particles.

Ahmed et al. disclose a killed cholera vaccine, which is lyophilized (see page 837; abstract). As the lyophilized vaccine of Ahmed et al. comprises dried particles, the disclosure of Ahmed et al. anticipates the limitations of the instant claims.

Moreover, it should be remembered that the products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same or similar functional characteristics, i.e. prophylactic activity. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when the process does not change properties of the product in an unexpected manner. See *In re* Thorpe, 227 USPTO 964 (CAFC 1985); *In re* Marosi, 218 USPTO 289, 29222-293 (CAFC 1983); *In re* Brown, 173 USPTO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with

which the increased purity, great stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts to applicants product in order to overcome the aspect of the product's purity.

7. Claim 69 is rejected under 35 U.S.C. 102(b) as being anticipated by Terman (U.S. Patent 6,251,385 B1).

Claim 69 is drawn to a vaccine composition made by a method comprising atomizing a liquid formulation of a therapeutic or prophylactic agent to produce an atomized formulation, freezing said atomized formulation to form solid particles, and drying said solid particles to produce dried particles.

Terman discloses a composition comprising *Staphylococcal enterotoxin* B, which has been filter sterilized, frozen, and lyophilized (column 19, lines 8-12). As the lyophilized vaccine of Terman comprises dried particles, the disclosure of Terman anticipates the limitations of the instant claims.

Moreover, it should be remembered that the products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same or similar functional characteristics. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when the process does not change properties of the product in an unexpected manner. See *In re* Thorpe, 227 USPTO 964 (CAFC 1985); *In re* Marosi, 218 USPTO 289, 29222-293

(CAFC 1983); *In re* Brown, 173 USPTO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, great stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts to applicants product in order to overcome the aspect of the product's purity.

A claim limitation such as "a vaccine " is being viewed as limitations of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the art. See *In re Casey,* 152 USPQ 235 (CCPA 1967) and *In re Otto,* 136 USPQ 458, 458.

8. Claims 69 and 71 are rejected under 35 U.S.C. 102(e) as being anticipated by Sasaki et al. (U.S. 2006/0024322 A1).

Claims 69 and 71 are drawn to a vaccine composition made by a method comprising atomizing a liquid formulation of a therapeutic or prophylactic agent to produce an atomized formulation, freezing said atomized formulation to form solid

particles, and drying said solid particles to produce dried particles. The claims are further drawn to a vaccine that is a recombinant *Staphylococcal enterotoxin* B vaccine.

Sasaki et al. disclose that *Staphylococcal enterotoxin* B (SEB) modifications or derivatives thereof are formulated into prophylactic/ remedies. The vaccine may be in the form of a powder (solid). A preferred embodiment includes SEB modifications or derivatives which are lyophilized (see paragraph 0048). As the lyophilized vaccine of Sasaki et al. comprises dried particles, the disclosure of Sasaki et al. anticipates the limitations of the instant claims.

Moreover, it should be remembered that the products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same or similar functional characteristics. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when the process does not change properties of the product in an unexpected manner. See *In re* Thorpe, 227 USPTO 964 (CAFC 1985); *In re* Marosi, 218 USPTO 289, 29222-293 (CAFC 1983); *In re* Brown, 173 USPTO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, great stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary

consideration which the additional degree of purity imparts to applicants product in order to overcome the aspect of the product's purity.

9. Claim 69 is rejected under 35 U.S.C. 102(e) as being anticipated by Hwang et al. (U.S. 2003/0186271 A1).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim 69 is drawn to a vaccine composition made by a method comprising atomizing a liquid formulation of a therapeutic or prophylactic agent to produce an atomized formulation, freezing said atomized formulation to form solid particles, and drying said solid particles to produce dried particles.

Hwang et al. disclose a method of preparing a pharmaceutical composition comprising one or more of the following steps: atomizing a liquid formulation of a therapeutic or prophylactic agent to produce an atomized formulation; freezing said atomizing formulation to form solid particles (see paragraph 0032).

A claim limitation such as "a vaccine " is being viewed as limitations of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably

distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the art. See *In re Casey,* 152 USPQ 235 (CCPA 1967) and *In re Otto,* 136 USPQ 458, 458.

10. Claim 69 is rejected under 35 U.S.C. 102(e) as being anticipated by Hwang et al. (U.S. 2003/0180755 A1).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim 69 is drawn to a vaccine composition made by a method comprising atomizing a liquid formulation of a therapeutic or prophylactic agent to produce an atomized formulation, freezing said atomized formulation to form solid particles, and drying said solid particles to produce dried particles.

Hwang et al. disclose a method of preparing a pharmaceutical composition comprising one or more of the following steps: atomizing a liquid formulation of a therapeutic or prophylactic agent to produce an atomized formulation; freezing said atomizing formulation to form solid particles (see paragraph 0035).

A claim limitation such as "a vaccine " is being viewed as limitations of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the art. See *In re Casey,* 152 USPQ 235 (CCPA 1967) and *In re Otto,* 136 USPQ 458, 458.

Since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJP
1/17/07

ROBERT A. ZEMAN
PRIMARY EXAMINER